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IN THE

Supreme Court of the United States

OCTOBER TERM, 1967

DR. F. ALLEN RUTHERFORD, Louise Walther, Sally Ranich, Vera Mae Jeffries, C. R. Easter, Dorothy Williams, each in behalf of their own person, and in behalf of all persons afflicted with cancer, and approximately thirty-two million Americans now living who will die with cancer,

Petitioners,

vs.

THE AMERICAN MEDICAL ASSOCIATION, INC., an Illinois Corporation, The American Cancer Society, Inc., a New York Corporation, The American Cancer Society, San Francisco Division, California, and Dr. ———— Batchelder (first name unknown) and

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, Dr. Warren G. Cole, Dr. Danley Slaughter, Dr. Virginia Pierce, Dr. George D. Stoddard, and

DR. KENNETH M. ENDICOTT, Arthur Furst, Paul Kirk, Gene R. Hay, Michael Deddish, Joseph M. Regan, Guy F. Robbins, Albert Segaloff, Austin Smith, Henry A. Szujewski, Paul Wermer, Oliver Field, R. Edwin Moore, Daniel Abrahamson, John William Blue, Mrs. John W. Blue, Carl R. Baurlen, William E. Braunig, R. W. Case, Joseph Cox, Gilbert Goldhammer, John R. Heller, William Kupp, Boisfeullet Jones, George P. Larrick, T. C. Maariveglia, Howard Mayfield, Willard G. Orr, Robert Palmer, Thomas Rice, George Schwartzman, Clifford Shane, R. D. Sherman, Ted J. Smolenski, Norman P. Booker, and other persons unknown,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

Petitioners pray that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Seventh Circuit entered in the above case on June 23, 1967.

OPINION BELOW

The opinion of the Court of Appeals for the Seventh Circuit is reported at 379 F. 2d 641; and is printed in the Appendix hereto, *infra*, App. 1-7; and the unreported opinion of the District Court in Appendix at *infra*, pp. App. 8-16.

JURISDICTION

The jurisdiction of this Court is invoked under 28 U.S.C. Section 1254(1).

QUESTIONS INVOLVED

1. Where the proximate consequences of the criminal conspiracy allegedly conducted by the respondents in violation of the antitrust laws, is actual and threatened loss and damage to the lives and rights of the petitioners, are the petitioners entitled to sue for and have injunctive relief against such threatened loss and damage under section 26, Title 15, U.S.C.?

2. Whether private corporations and private individuals, acting in association with public officials under color of law from the University of Illinois, in a criminal conspiracy in violation of the antitrust laws, come within the scope of sections 1983-1985, Title 42, U.S.C.

3. Where a corporation, such as the American Medical Association, vested with sufficient economic power and influence concentrated in this State-created vehicle to invade the rights secured by the Constitution and laws of the United States of 200,000 Americans to a material degree,

conducts a criminal conspiracy in violation of the antitrust laws, does such wrongful conduct come within the prohibitions contained in the Fourteenth Amendment?

4. Whether a corporation, such as the American Cancer Society which, to a material degree, has substantial control of research on cancer in the United States, and exclusively exists on grants-in-aid funds from Federal and State Governments, and tax exempt and tax deductible contributions from the public, when it is associated with another corporation, four State University Officials, and a series of individuals in a criminal conspiracy which violates the antitrust laws, comes within the scope of the prohibitions of the Fourteenth Amendment.

5. Whether the toleration of a "monopoly in the trade of medicine" by the American Medical Association is legally and socially defensible and justified when perverted so as to conduct, with others in this case, a criminal conspiracy in violation of the antitrust laws "of vigilante-like activities", restraining doctors in pursuit of their calling, depriving them of hospital facilities for their patients, threatening them with disciplinary action, excluding them from hospital staffs, both in private and State hospitals, depriving them of consultation with other members of the profession on pain of expulsion, because of administering or seeking to administer to their patients in scientific and experimental research, a therapy legally in interstate distribution for such purpose, which they believed and still believe showed and shows promise of making valuable contributions to human knowledge in the cause and treatment of cancer; and further, is the toleration of such monopoly when so exercised in such a conspiracy, hus defensible and justified even if such interstate distribution is forbidden by law.

6. Whether such a conspiracy is defensible because the therapy has not been approved under the Federal Food, Drug, and Cosmetic Act, and because the respondents disagree with the scientific expertise of the Department of Health, Education, and Welfare and its determinations twice in 1954, and once in 1961, that the therapy, because of its components, does not come within the provisions of that Act but under the Public Health Service Act of 1944, and that nothing could be gained by any application to the provisions of the former.

7. Whether, in amending section 355 (i), Title 21, U.S.C., in October 1962, effective in June 1963, Congress set up such a right, which respondents claim as their sole defense, as to justify such a criminal conspiracy, both retroactively from its conception in 1950, and in the present.

8. Whether, the determinations of the Department of Health, Education, and Welfare, based on the conclusions of its scientific expertise made on May 25, 1954, August 12, 1954, and on June 9, 1961, that Krebiozen, because of its components, "is subject to the Virus, Serum, and Toxin provisions of the Public Health Service Act of July 1944," and that "Nothing is to be gained by considering the product as a new drug under the Food, Drug, and Cosmetic Act," and that "Our scientists, on the information submitted, classify this drug as an 'analogous product' within the meaning of the Public Health Service Act," and that "We recommend that you abandon the idea of pursuing an effective new drug application and submit an appropriate application for licensing of Krebiozen by the Division of Biologic Standards," may be completely ignored or overruled by the respondents and the courts below as a refutation of their defense to the allegations of such a criminal conspiracy.

9. Whether section 262, Title 42, U.S.C., the Public Health Service Act, a highly penal statute, directed against persons who "sell, barter, or exchange, or offer for sale, barter, or exchange," in interstate commerce, is applicable to articles which come within the provisions of the Act, but are distributed interstate, not for "sale, barter, or exchange," but for use in scientific and experimental research, with the elements of "sale, barter, or exchange," precedent to a conviction under the statute, totally absent.

10. Whether the amendment of section 355 (i), Title 21, U.S.C., effective June 1963, expressly limited to drugs where there can be a valid "event of the filing of an application pursuant to subsection (b) of this section," to put the article in interstate commerce, can be extended by regulation, unauthorized by legislation, to articles like Krebiozen, where the only valid "event" for introducing the article in interstate commerce is an application pursuant to section 262, Title 42, U.S.C., as has been thrice determined by the Department of Health, Education, and Welfare.

11. Whether Congress has, in such amendment enacted a law not naturally or reasonably adapted to the power conferred by the Commerce Clause, but solely adapted to the achievement of the regulation of the practice of medicine which is reserved solely to the States and the People, by the Ninth and Tenth Amendments, and which practice involves no elements of commerce.

12. Whether such a criminal conspiracy of official lawlessness as the record here reveals, dedicated and calculated to effectively stifle independent initiative and originality in the "Progress of Science and the useful Arts," and designed to impede and hinder those already skilled in the profession of medicine, to attempt new

methods of treatment for cancer, when all other known methods have proved futile, and particularly when the patient's life has been despaired of, especially when undertaken with the patient's full knowledge and consent, and as a last resort, violates Article 1, section 8, the Fifth, Ninth, Tenth, and Fourteenth Amendments of the Constitution, and is of such immense social significance as to warrant review by this Court on certiorari.

13. Whether *Turkel* v. *Food and Drug Administration,* 334 F. 2d 844, where the subject matter comes under a different law because it deals with an essentially different product, subject to different regulations, have any application here.

14. Whether the District Court did not commit a fatal error on May 13, 1966, when it denied to the petitioners the right to file a verified petition for a mandatory temporary injunction under Rule 65, Federal Rules of Civil Procedure, and a finding of facts and conclusions of law as mandatorily provided by Rule 52, despite the fact that the petition supported by affidavits and exhibits made a strong showing that irreparable damage to the health and lives of the petitioners was imminent, and which denial has directly contributed to the death of three of the petitioners since that time.

15. When it was brought to the notice of the District Court on February 4, 1966 by counsel for the petitioners that if a temporary restraining order or temporary injunction was not issued the lives of the petitioners would be in peril because of the criminal conspiracy, and the motion was denied on the grounds "This matter has been going on for a number of years, so there cannot be that kind of an emergency here today," not a fatal error.

16. Whether a citizen afflicted by disease, and especially when declared terminal, has a constitutional right under the Fifth, Ninth and Fourteenth Amendments to freedom of access of a non-toxic medical remedy of his own choice regardless of sanction thereto by the American Medical Association or Governmental Agencies or bureaucrats.

17. Whether the Federal Food Drug and Cosmetic Act, as amended in 1961, is unconstitutional because violating the rights of individuals, under the Fifth, Ninth and Fourteenth Amendments to the United States Constitution, whose survival depends upon unfettered access to a new drug, because such Act permits an arbitrary and judicially non-appealable denial of an application for investigational exemption therefrom and permits half a year's delay by the Secretary of Health, Education and Welfare in consideration of an application for approval of interstate distribution and further fatal delay in administrative and judicial appeals to an arbitrary refusal of such application.

CONSTITUTION, STATUTES, FEDERAL RULES OF CIVIL PROCEDURE, AND DRUG REGULATIONS INVOLVED.

Involved herein are the following: Amendments Five, Nine, Ten, and Fourteen of the Constitution of the United States App. F., App. 29 in Appendix; Section 26, Title 15, U.S.C.; Section 355, Title 21, U.S.C., Section 1331, 1343, Title 28, U.S.C., Sections 262, 284, 1983, 1984, 1985, Title 42, U.S.C.; Federal Rules of Civil Procedure 52 and 65; Food and Drug Regulations 130.3, all in appendix pp. App. 22-39.

STATEMENT

This suit was commenced on January 3, 1966 in the United States District Court in Chicago by the filing of a Complaint praying for a Mandatory Injunction against the Respondents.

On January 10th and 13th, 1966, the petitioners filed with the District Court two petitions for temporary restraining orders returnable on Jannay 19, 1966 (Vol. II, pp. 326-334, R.)

On January 19, 1966 the case was continued until February 4, 1966.

On February 4, 1966, the petitions for the restraining orders were denied (Vol. II, 326-385, R).

On May 6, 1966, the petitioners filed with the District Court a Verified Petition For A Mandatory Temporary Injunction. On May 13, 1966, the District Court ordered the Clerk to delete the filing numbers from the petition and denied the petitioners the right to file the Petition (Vol. II, 501-512, R).

On July 18, 1966, the Complaint was dismissed with an opinion (Copy annexed at pp. App. 8-16).

On July 26, 1966, the petitioners filed notice of appeal to the Court of Appeals (Vol. II, 540-543, R).

On November 2, 1966 the Court of Appeals denied a petition for a temporary injunction pending appeal (Vol. III, p. 221).

On June 23, 1967, the Court of Appeal affirmed the decision of the District Court with opinion reported at 379 F. 2d 641, (copy in appendix, pp. App. 1-7).

On September 13th, 1967, Mr. Justice Fortas granted the petitioners an extension of time up to and including November 19, 1967 in which to file petition for certiorari in this Court (copy of order in appendix at p. App. 40).

SUMMARY OF ALLEGATIONS

1. Krebiozen upon its original introduction in this country by Dr. Stevan Durovic in 1949 having already shown promise in extensive animal research, showed promise in the control of cancer in man. It was used experimentally on terminal patients by a number of doctors and institutions such as Lankenau Hospital Research Institute of Philadelphia (See Exhibit 3 of Amended Complaint for their favorable report; Amended Complaint Vol. 1) the Marquette Tumor Clinic, the Walter Reed Hospital and Johns Hopkins Hospital.

Dr. Andrew C. Ivy, who had for a long time been interested in cancer research, and had postulated that cancer, although manifesting itself in differing symptoms was possibly caused by a single fundamental body deficiency, investigated Krebiozen with, to him, remarkable results and recoveries in apparently hopeless cancer patients. (This is outlined in pp. 42, 46, paragraphs 154 and 176, Amended Complaint Vol. I).

2. The initial phase in the criminal conspiracy alleged in the Amended Complaint commenced when several of the perennial officers of the American Association, learning of the promise of Krebiozen endeavored to obtain its commercial control for them and their business associates. They were rebuffed by Dr. Durovic and his brother who was financing him. (This phase of the conspiracy it outlined in pages 39 through 46 paragraphs 143-146 and 153-176, Amended Complaint, Vol. 1). From then on these men commenced a systematic campaign to destroy Krebiozen.

During this time Dr. Ivy and his associates endeavored to have a committee of scientists sponsored by the American Medical Association, review his experience with Krebiozen and that of the above mentioned institutions and hospitals. On the request of the American Medical Association he submitted 140 representative clinical records of patients he had treated with Krebiozen (See pages 50 and 51, paragraphs 197-203, Amended Complaint, Vol. 1).

3. The initial phase in the alleged criminal conspiracy culminated in what was classified as the Status Report on Krebiozen by the American Medical Association and was published in the Journal of the American Medical Association on September 27, 1951. As was subsequently revealed under oath at Hearings held before an Illinois Legislative Committee this Report was a deliberate fraud, and was designed and calculated to suppress the anticancer nontoxic therapy named Krebiozen. This therapy showed promise of making valuable contributions to human knowledge in the cause and treatment of cancer, but if it should prove effective and be introduced into medicine it would be in economic conflict with such alleged therapies as surgery, radiation, cobalt, and highly toxic therapies, all of which are applied to the effects of the disease, and not the cause, and all in complete control of the Respondent, the American Medical Association. This phase of the conspiracy consumed about a year and was conducted by the conspirator Dr. J. J. Moore, the Respondents Dr. Austin Smith, Dr. Paul Wermer, and Oliver Field, and others unknown, acting as officers of the American Medical Association, and in concerted action with the Respondent R. Edwin Moore, a private individual, Dr. Albert Segaloff, representing the Oschner Cancer Clinic of New Orleans, the Respondent Dr. Henry A. Szujewski all in behalf of the American Medical Association, and the Respondents Dr.

Warren G. Cole, Dr. Virginia Pierce, and Dr. Danley Slaughter, acting "under color" of law from the University of Illinois, and in concerted action with the Respondent, the American Medical Association. This phase represented the suppression completely of the 140 clinical case records which, had been by agreement between Dr. Andrew C. Ivy and the American Medical Association, would be used as the base on which to determine the effectiveness of Krebiozen in the control of cancer. These clinical records of patients who had been treated with Krebiozen came from some of the most reputable hospitals in the United States, and all of them, without exception, indicated that the therapy did show promise of making valuable contributions to human knowledge in the treatment of the disease. Twenty four additional clinical records of patients treated with Krebiozen were submitted by Dr. Andrew C. Ivy. These records came from a private physician from Chicago named Dr. William F. Phillips. Like the 140 clinical records from the hospitals, these records from Dr. Phillips also indicated that this therapy showed promise in controlling cancer. The Respondent Dr. Henry A. Szujewski forged and uttered 23 out of the 24 clinical records to make it appear otherwise. The conspirator Dr. J. J. Moore, and the Respondents Dr. Austin Smith, Dr. Paul Wermer from the American Medical Association, Dr. Albert Segaloff from the Oschener Cancer Clinic of New Orleans, and Dr. Warren G. Cole, Dr. Virginia Pierce, acting "under color" of law from the University of Illinois through the Illinois Tumor Clinic, then implemented a common scheme and plan systematically to select from these clinics and others, the clinical records of cancer patients who were on the edge of the grave and could not, and did not, live long enough to receive in some instances more than one, and in no instance more than four, injec-

tions of Krebiozen. All those patients who had received more injections of the therapy and where it did show promise of making valuable contributions to human knowledge in the treatment of cancer were systematically disregarded. 100 clinical records of the former were used for the investigation. On these systematically selected clinical records the determination was based. They numbered 76 and with the 24 clinical records, 23 of which Dr. Henry A. Szujewski had uttered the Status Report of Krebiozen was grounded. All this was subsequently also revealed under oath at the Hearings held before the Illinois Legislative Committee. As a follow-up of this fraudulent and partly uttered Status Report, on the instructions from the conspirator Dr. J. J. Moore and Dr. Paul Wermer, Dr. Henry A. Szujewski wrote another article in the Journal of the American Medical Association which was published on March 27 1952. This article was also false. (The acts of each and every one of these Respondents in this phase of the conspiracy and fraud are outlined with particularity in pp. 33-66, paragraphs 143-269, Amended Complaint, Vol. 1).

4. The next phase in the criminal conspiracy and directly linked with phase one, culminated in the publication of the "Conclusions" and "Recommendations" purportedly drawn from the Report of the Krebiozen Validating Committee by the University of Illinois and released to the world by the Respondents Dr. George D. Stoddard and Dr. Warren G. Cole on September 20, 1952. Both the "Conclusions" and the "Recommendations" were a fraud because they were not those of the Committee, were not based on the facts of the "Main Report" of the Committee, were not authorized by the Committee, were not signed by any of the other five members of the Committee, and no

member of the Committee knew of the release until it was a *fait accompli.* The Respondent Dr. George D. Stoddard, because the Main Report of the Committee indicated from the physical examination of a series of cancer patients by members of the Committee and a great many clinical records which were presented to the Committee that Krebiozen did show promise of making valuable contributions to human knowledge in the cause and treatment of cancer, suppressed and hid the Main Report, and even refused Dr. Andrew C. Ivy to examine the Main Report. Over one month after the release of the "Conclusions" and "Recommendations" by Dr. George D. Stoddard and the Respondent Dr. Warren G. Cole, on the instructions of the conspirator Dr. J. J. Moore, and the Respondent Dr. Paul Wermer, the five other members of the Committee, Dr. N. C. Gilbert, Dr. Fred Hodges, Dr. Robert W. Keeton, Dr. Paul Steiner, and Dr. Owen H. Wangensteen, were compelled to sign a blank signature sheet, without having been permitted to even read a copy of the "Recommendations." The single sheet was sent out by the Respondent Dr. George D. Stoddard in a chain form letter to these members of the Committee (The facts which constitute this phase of the fraud and conspiracy are outlined with particularity in pp. 66-97, paragraphs 270-407, in the Amended Complaint, Vol. 1, Record. The facts are borne out by sworn testimony in the subsequent Hearings of the Committee of the Illinois General Assembly).

5. In March, 1954, the sponsors of Krebiozen filed an application under subsection 355 (b) of Title 21, U.S.C.A. (The Federal Food, Drug, and Cosmetic Act) in order to place Krebiozen in interstate commerce. On May 25th, 1954, the application was rejected on the grounds that " . . . it is the considered view of the Department of Health,

Education, and Welfare that Krebiozen is subject to the Virus, Serum, Toxin provisions of visions of the Public Health Service Act of July 1944, and that the article may not be legally marketed in interstate commerce until licensed under the provisions of that Act. #. . . When a license is issued by that unit of the Department, an effective new drug application is not required. #Even if a new drug application became effective for the article, it would still be necessary that it be licensed under the provisions of the Public Health Service Act in order that it be distributed in interestate commerce. #Nothing is to be gained by considering the product (Krebiozen) as a new drug under the Food, Drug, and Cosmetic Act."

6. Shortly after the scientific determination was made by the Department of Health, Education, and Welfare that Krebiozen was not a "new drug" within the provisions of the Federal Food, Drug, and Cosmetic Act, but came exclusively within the provisions of the Public Health Service Act which is Section 262, Title 42, U.S.C.A., the sponsors of Krebiozen offered more data to show that Krebiozen did come within the provisions of the Federal Food, Drug and Cosmetic Act. The Department of Health, Education, and Welfare, on August 12, 1954, reiterated its former scientific determination of May 25, 1954 that: "Our scientists, on the information submitted, classify this drug (Krebiozen) as an 'analogous product' within the meaning of the Public Health Service Act. #Since the drug, in the Department's view, may not be distributed for barter or sale unless produced in a licensed establishment, we recommended to you in our letter of May 25, that you take the problem up with the Laboratory of Biologics Control rather than pressing for an effective new drug application . . . #We do not insist on the needless dublication of satisfying the requirements of both laws. We do insist,

however, that products subject to license control meet the requirements of the Public Health Service Act. . . . #We renew our recommendation that you take steps to obtain a license rather than making further efforts to complete the new drug application." After this second determination of the scientific expertise of the Department of Health, Education, and Welfare, the sponsors of Krebiozen limited interstate distribution of Krebiozen to doctors throughout the United States who were fully qualified by scientfic training and experience to investigate the safety and effectiveness of drugs, but not for "sale, barter, or exchange" exclusively for "use in scientific and experimental research." This was in strict conformity with section 262, Title 42, U.S.C.A. (The Public Health Service Act) and with the ruling by the Attorney General in 29 Opinion of Attorney General 340.

7. Shortly thereafter the determination of the scientific expertise of the Department of Health, Education, and Welfare, Dr. Andrew C. Ivy, the scientific sponsor of Krebiozen received a grant-in-aid from the Lakeland Foundation of Chicago for the purpose of producing Krebiozen to carry out this program of "scientific and experimental research". The American Medical Association then launched another phase of the continuing conspiracy, to prevent this program from being implemented, through its chief security officer, the Respondent, Oliver Field. The facts which constitute this phase are stated with particularity at pp. 97-106, paragraphs 408-466, Amended Complaint, Vol. 1, Record). Simultaneously in this phase, the American Medical Association launched a campaign of harassment against doctors using the therapy and patients receiving it. The harassment tactics employed against these doctors and their cancer patients had a striking similarity to the tactics used by the Respondent,

the American Medical Association and its affiliated medical societies in the criminal conspiracy against Group Insurance outlined in the indictment of *American Medical Association* v. *United States*, 317 U.S. 519, at pages 7-19, Volume 1, Record on Certiorari, on file in this Court.

8. As the result of the Hearings by the Illinois General Assembly the first report of that Assembly was handed down on June 30, 1955 and the following public policy was adopted by the Legislative Body for the State of Illinois to further investigate Krebiozen because "It is evident there are citizens in Illinois and other states and countries who are or have been afflicted with the dread disease, cancer, and who received treatment by medical practitioners by the use of the drug Krebiozen and are today alive and well; and after a period of ten years, Krebiozen continues to hold out very substantial promise and assurance that there must exist merit and truth within the drug Krebiozen to manage and control cancer in the patient;" (pp. 96-97, paragraphs 403-407, Amended Complaint, Vol. 1, Record).

9. Subsequent to the first report of the Illinois Legislative Assembly and the harassment by the American Medical Association through its chief security officer, the Respondent, Oliver Field, the conspiracy changed venue to New York and California and involved the Respondent, the American Cancer Society, the Respondents, Dr. Batchelder, the Chairman of its San Francisco branch, Arthur Furst, Paul Kirk, and Dr. John R. Heller, the latter of whom held positions involving a conflict of interest. He was both director of the American Cancer Society and at the same time was the director of the Government Health Institution, the National Cancer Institute, and was being paid for both. For all practical purposes Dr. John R.

Heller is the first connecting link with private individuals and private corporations on one hand, and individuals employed by the United States Government on the other hand. After negotiations between Dr. Andrew C. Ivy the scientific sponsor of Krebiozen and representatives of the American Cancer Society, the latter undertook to formulate a paper on "The Background of Krebiozen," despite the fact that any favorable Report on the non-toxic therapy Krebiozen if favorable would be in economic conflict with the vested interests of the American Cancer Society. At the time, this Society owned about 50% of the highly toxic anticancer substance known as 5-FU and if it was determined that Krebiozen did show great promise of making valuable contributions to human knowledge in the cause and treatment of cancer this would render the highly economic vested interest in 5-FU by the American Cancer Society at naught. For this reason the American Cancer Society proceeded to condemn Krebiozen in a studied campaign to falsify and a premeditated determination to so condemn. The facts which constitute the fraud and conspiracy are outlined with particularity as to each Respondent involved in this phase in pp. 107-138, paragraphs 447-595, Amended Complaint, Vol. 1, Record). In pursuance of this plan the "Paper on the Background of Krebiozen" was issued on March 9, 1959 condemning Krebiozen.* While the so-called

* As later determined this paper was in fact based upon the perjured statements of two "researchers" to the effect that with no more than six unregistered ampules they had conducted very many and radically differing exhaustive tests, which however, scientifically, would have required at least several hundred valid ampules and had "found" that Krebiozen is no more than "mineral oil".

investigation was pending the Respondent, Dr. John R. Heller had been conducting negotiations with Dr. Andrew C. Ivy with the objective of a "double blind" test for Krebiozen by the National Cancer Institute. But as Dr. Heller had voted as a paid director of the Respondent, the American Cancer Society, and in full awareness of how that determination was brought about by fraud and misrepresentation, he was in no position to overrule it as the director of the National Cancer Institute. Prior to the voting for the condemnation of Krebiozen he had agreed with the sponsors of the substance that the double-blind test was "the standard of evaluation at the National Cancer Institute." He had now voted with the American Cancer Society as its director that the double-blind test was "unscientific." Further negotiations for a test as provided by section 284, Title 42, U.S.C.A. (The Public Health Service Act) where the scientific expertise of the Department of Health, Education, and Welfare determined that Krebiozen had belonged were futile. In 1960 Dr. Heller ceased his role of conflicting interests and retired as director of the National Cancer Institute to take an executive position with Sloan-Kettering Memorial Institute in New York. He was replaced as director of the National Cancer Institute by the Respondent, Dr. Kenneth M. Endicott on July 1, 1960.

10. The sponsors of Krebiozen immediately commenced negotiations with the Respondent, Dr. Endicott for a test of the therapy under section 284, Title 42, U.S.C.A. Dr. Endicott agreed to have the National Cancer Institute test the drug, Krebiozen, as provided by that statute. See pages 138-148, paragraph 596-647, Amended Complaint, Vol. 1, Record. Adequate data to be used as a guide to the test was submitted to Dr. Endicott on or about October 20, 1960, at a meeting with all the parties in the Lord

Baltimore Hotel, Baltimore, Maryland (p. 146, par. 637, Amended Complaint) and it was further clearly understood between Dr. Endicott and the sponsors that the material and data submitted to Dr. Endicott by the sponsors was to be used as a guide to the test agreed upon, and would not be submitted to any committee to decide whether or not a test would be made. Instead of honoring the agreement, Dr. Endicott gave the data, which contained the names of over 3,000 physicians over the United States who had successfully treated their patients with Krebiozen, over to the Respondent, George Larrick, who immediately launched a wide-spread harassment campaign against these doctors and their patients never before heard of in the entire history of the suppression of innovation in the medical world. Simultaneously with this campaign of harassment was also launched a widespread campaign of entrapment practices against the sponsors of Krebiozen and many of the doctors. The phase culminated in a secret committee of systematically selected scientists, half of whom depended on Dr. Endicott for their income from Government grants approved by Dr. Endicott, in a predetermined scheme and plan to condemn Krebiozen without a hearing. This phase of the conspiracy and fraud is outlined with particularity as to each and every respondent involved in its execution in pp. 148-225, paragraphs 648-1014, Amended Complaint, Vol. 1, Record.

11. Early in 1961 the sponsors of Krebiozen again filed an application under the Federal Food, Drug, and Cosmetic Act, section 355 (b), Title 21, U.S.C.A. to place the substance in interstate commerce. This was again rejected in June, 1961 by the Department of Health, Education and Welfare on the grounds that the substance did not come within the provisions of this Act, and the Department stated that : "We recommend that you abandon the

idea of pursuing an effective new drug application and submit an appropriate application for licensing by the Division of Biological Standards, National Institutes of Health, U. S. Public Service." However, were it not for the determination of the Department of Health, Education and Welfare that Krebiozen is not a new drug and does not come under the Federal Food, Drug and Cosmetic Act, that application under that Act would be effective today because the Secretary failed to comply with the provisions of Section 355 (c) of that Act and as a result, by reasons of the terms of the Act the application became automatically effective upon the expiration of the prescribed statutory time.

12. Thereafter on September 7, 1963, the Food and Drug Administration publicly released a report that it had determined that Krebiozen was (not mineral oil but) only Creatine, a harmless but ineffective body substance. This report used infra-red spectograph overlays patently juggled by seven and one-half percent to force coincidence of graph lines and disregarded gross chemical differences in acids, sugars, molecular weight and carbon content between Krebiozen and Creatine which were already known to that administration and the National Cancer Institute. (This phase of the conspiracy and fraud is outlined in pages 171 through 182, paragraphs 777 through 818 and page 189, paragraphs 856 through 858, Amended Complaint Vol. I).

13. Thereafter on October 16, 1963, the National Cancer Institute published a report of a Secret Committee of 24 doctors (of whom it was later determined 8 were on the United States Government payroll and the other 16 were recipients of large Government research grants). This report, which was expressly based on the Food and Drug Administration that Krebiozen is only ineffective creatine,

denied that any weight should be given to its value as a pain reliever (because pain, being subjective, is not susceptible of objective proof) and, after scrambling the identification numbers of the cases, disregarding 216 cases without disclosed justification (of which 15 were later determined to be very favorable breast cancer cases), of the remainder all where 50% or less reduction of tumor (even though still continuing) were involved and of 15 cases nevertheless meeting these uniquely restrictive standards disregarded all but two by increasing the unique and irrational severity of the standards applied and concluded that the remaining two were due to spontaneous regression (notwithstanding that hitherto the classic Cole-Everson study of four and one-half million cancer cases indicated that spontaneous regression occurs in only one out of 80,000 to 100,000 cases). (This phase of the conspiracy and fraud is outlined in pages 153 through 171, paragraphs 699 through 776 and pages 184 through 222, paragraphs 829 through 1007, Amended Complaint, Vol. I).

14. Dr. Ivy and his associates were refused publication in any medical journals controlled by the American Medical Association of numerous, voluminous, scientifically exhaustive articles on clinical and experimental experience with Krebiozen and finally had to resort to private publication. Having denied him and his associates such publication, the American Medical Association then criticized Krebiozen, on the grounds that no papers on it had been published in their authoritative Medical Journals (See pages 135 through 137, paragraphs 584 through 593, Amended Complaint, Vol. I).

REASONS FOR GRANTING THE WRIT

The subjects in the numbered paragraphs here correspond with the subjects in the same numbered paragraphs in the "QUESTIONS INVOLVED."

1. The petitioners are entitled to sue for and have injunctive relief under section 26, Title 15, U.S.C.A.

It has been well settled in this Court that the Sherman-Clayton Act gives to private persons he right to sue for and have injunctive relief against threatened loss or damage by violations of the anti-trust laws where the threatened loss or damage is the proximate result of the violations, and the cause of action, or the right to sue is not dependent upon any relationship, contractual or otherwise, between the claimant and the offender because these statutes giving relief do not confine their protection "to consumers, or to purchasers, or to competitors, or to sellers. Nor does it immunize the outlawed acts of any of them. The Act is comprehensive in its terms and coverage, protecting all who are made victims of the forbidden practices by whomever they may be perpetrated." *Mandeville Island Farms, Inc.* v. *American Crystal Sugar Company*, 334 U.S. 219, 236, and cases cited. To the same extent is section 26, Title 15, U.S.C.

2. The respondent private corporations and individuals acting with public officials under color of law in this alleged criminal conspiracy violating the anti-trust laws are subject to the restraints of the Civil Rights Acts.

It has long been well settled by this Court that the conduct of private persons and private corporations is subject to the prohibitions of the Fourteenth Amendment when

a State, through its officers, "has so far insinuated itself into a position of interdependence * * * that it must be recognized as a joint participant in the challenged activity." *Burton* v. *Wilmington Parking Authority*, 365 U.S. 715, 725.

And that "private persons, jointly engaged with State officials in a prohibited action, are acting 'under color' of law for the purposes of the State. It is enough that he is wilfull participant in the joint activity with the State or its agents." *United States* v. *Price*, 383 U.S. 787. The participation of the respondents Dr. George D. Stoddard, president of the State University of Illinois, and Dr. Warren G. Cole, Dr. Danley Slaughter, and Dr. Virginia Pierce, all officers or agents of the State University of Illinois, a State Institution, bring the entire conspiracy within the prohibitions of the Fourteenth Amendment and the Civil Rights Act because those corporations and private individuals who took advantage of participation by State officers must suffer the consequences of that participation. "They were participants in official lawlessness, acting in Wilfull concert with State officers and hence under color of law." *United States* v. *Price*, 383 U.S. 787. The language of sections 1983-1985, Title 42, U.S.C. embraces "*all* of the rights and privileges secured to citizens by *all* of the Constitution and *all* of the laws of the United States." *ibid.* This includes the Sherman Anti-Trust Act.

3. The American Medical Association is subject to the Fourteenth Amendment, and therefore to the restraints of the Sherman Anti-Trust Act, when it conducts an illegal conspiracy such as that alleged.

The preconditions for the application of the prohibitions of the Fourteenth Amendment is so far as the American Medical Association is concerned are two: (1) The undeniable fact that this Association is a creature of the State of Illinois, and (2) that this corporation is vested with sufficient economic power and influence concentrated in the State-created vehicle to invade the rights and privileges secured by the Constitution and laws of the United States of 200,000,000 Americans to a material degree. It is sufficient that the manifestations of this concentrated power and the influence which goes with it, as a practical matter, have a significant influence over the lives of a great number of the American People, either nationally, or in a State, City, or even in a small town. *Marsh* v. *Alabama*, 326 U.S. 51; Fruend, *Individual and Commonwealth Thought of Mr. Justice Jackson*, 8 Stan. L. Rev. 6; Lewis, *The Meaning of State Action*, 60 Col. L. Rev. 1083, 1122; *Hawkins* v. *North Carolina Dental Society*, 355 F. 2d 718. The vice stems from power. It is of no significance whether this power derives its source from the ownership of property, from control of professional services which the people require as a whole, or control of particular products or services. The American Medical Association has such power. It has absolute control by statute, formal rule or formal policy or informal policy, over state medical schools and examining boards which provide the only consideration of graduates of schools approved by it or the American Association of Medical Colleges whose lists are identical, and had substantial control over both the number of medical schools in the United States and the rate of production of doctors. As a practical matter, expulsion from this Association is the equivalent to the suspension of a license to practice medicine. Hyde and Wolff, *The American Medical Association, Power, Purpose, and Poli-*

tics in Organized Medicine, 63 Yale L. Jour. 969; Kessel, *History and Development of the Medical Monopoly,* Journal of Law and Economics, Vol. 1, October 1958, University of Chicago Law School, pp. 25-29. Even in the absence of direct State Action and participation in the conspiracy by officials of the State University of Illinois, the participation in the conspiracy by the American Medical Association brings the case within the prohibitions of the Fourteenth Amendment and Civil Rights Act, sections 1983-1985, Title 42, U.S.C. The business conducted by the American Medical Association is so necessarily entwined with government policies, and so impregnated with a government character "as to become subject to the constitutional limitations placed upon State Action." *Evans* v. *Newton,* 382 U.S. 296; *Terry* v. *Adams,* 345 U.S. 461.

4. The Respondent, the American Cancer Society, is also subject to the Fourteenth Amendment and therefore to the restraints of the Sherman Anti-Trust Act.

A New York State-created corporation such as the American Cancer Society with its nation-wide affiliates of the same name who submit 40 percent of their gross income to the parent Society, and this corporation having dominant control of cancer research in the United States, and therefore vast power and influence over the lives of a great many Americans afflicted with cancer, is subject to the prohibitions of the Fourteenth Amendment. What makes this more so is the fact that the corporation's entire income is derived from grants-in-aid from both Federal and State Governments, and contributions which are tax exempt and tax deductible donations. Like the American Medical Association, the conduct of the American Cancer Society is also so entwined with government policies, and so impregnated with a government character,

and its existence only possible through such funds from the pockets of the taxpayer, as to become also subject to the constitutional limitations placed on State action. *Evans* v. *Newton*, 382 U.S. 296; *Hawkins* v. *North Carolina Dental Society*, 355 F. 2d 718; Restatement (Second) Trusts, section 368 (1959); 4 Scott on Trusts, section 368, at 2629-2630 (2d ed. 1956); Bogart on Trusts, section 378 (2d ed. 1964); Lewis, The Meaning of State Action, 60 Col. L. Rev. 1083, 1092.

5. The American Medical Association is violating the legal and social sanction of its "monopoly in the trade of medicine" by joining in the alleged conspiracy under which it is perverting such monopolistic power to its own ends at the expense of humanity in general, and these Petitioners in particular.

The respondents admit the allegations in the complaint as to the violations of the Sherman Act, the Civil Rights Act, and the Constitution. These allegations were briefly outlined by counsel for the Board of Trustees of the University of Illinois on May 13, 1966 in the District Court (Vol. II, p. 504 R.) as follows:

> "This pleading which is before your Honor this morning accuses my client, the board of trustees of the University of Illinois, of participating in a criminal conspiracy which Mr. Hyde has gratuitously alleged is an established fact. It accuses all the defendants of forgery, fraud, a conspiracy to take economic advantage of sick people; it asserts that the conspiracy against Krebiozen is calculated and designed solely to perpetuate radiation treatment and surgery as the most expensive means of treating cancer."

The sole defense to the allegations charging a conspiracy appealed to for its justification, is an interpretation and enforcement of section 355(i), now section 505(i), Title

21, U.S.C. This is a statute which authorized the Secretary of Health, Education, and Welfare to promulgate regulations for drugs used solely for investigational use which come within the provisions of the Federal Food, Drug, and Cosmetic Act. This fictional defense was injected into the picture through an amendment of section 505(i) which became effective in June 1963. By this time the admitted conspiracy had endured for 13 years since 1950. The fiction was not available during this period because Krebiozen was being distributed interstate to licensed physicians for use in scientific and experimental research without question, and the sole restraint against such distribution arose exclusively from the conspiracy alleged. The Government did not seek, and has not sought, any injunctive sanctions against interstate distribution at any time during the past 17 years. However, even were Krebiozen prohibited interstate distribution by law or injunction in pursuance of such law, it has been well settled by the higher appellate courts and this Court that in an action arising from violations of the Sherman Act, or the Civil Rights Act, matters not affecting the respondents' responsibility such as the interpretation or enforcement of law cannot be set up as a defense against such violations. This was made clear in *American Medical Association* v. *United States*, 130 F. 2d 233, 246, affirmed 317 U.S. 519, where strikingly similar conspiratorial conduct was conducted by the American Medical Association in order to destroy Group Health in Washington, D.C. There it was said:

> "The licensed monopolies which professions enjoy constitute, in themselves, severe restraints upon competition. But they are restraints which depend upon capacity and training, not special privilege. Neither do they justify concerted criminal action to prevent the people from developing new methods of serving their needs. • • •

"* * * But they have no license to commit crime. When they go so far as to impose unreasonable restraints, they become subject to the prohibition of the Sherman Act. * * *

"Neither can justification for the commission of a crime be found in the fact that its commission benefited the community; and evidence offered for such a purpose is properly excluded. Nor is the fact that a crime was committed with the intent to accomplish some ultimate good, an excuse for its commission; *even if it was for the purpose of enforcing the law.*

"* * * And the same rule applies in cases of conspiracy under the Sherman Act. Neither the fact that the conspiracy may be intended to promote the public welfare, or that of the industry, nor the fact that it is designed to eliminate unfair, fraudulent and unlawful practices, is sufficient to avoid the penalties of the Sherman Act."

The sole defense in this case, like that in *United States* v. *American Medical Association,* 110 F. 2d 703, certiorari denied, 310 U.S. 644, is factual. As the Court said in that case:

"* * *we repeat, that the charge made here, and for the purposes of the demurrer admitted, is that the societies sought to restrain an association of persons of modest means from receiving medical services at lower cost and to coerce doctors and hospital to this end. The charge may be wholly unwarranted and the facts, when they are disclosed on the trial, may show an entirely different state of affairs, but for present purposes, we must take the charge as though its verity were established; and in that light, it seems to us clear that the offense is within the condemnation of the statute. It certainly cannot be doubted that Congress intended to exert its full power, in the public interest, to set free from unreasonable obstruction the exercise of those rights and privileges which are a part of our constitutional inheritance, * * * and any

undue restraint upon them is wrong and is immediate and unreasonable and, therefore, within the purview of the Sherman Act. (Cases cited).

As stated by the Court of Appeals in this case:

"Plaintiffs contend, however, that as long as this conspiracy remains unenjoined, it is immaterial whether or not Krebiozen is exempt from Government regulation. In their complaint, plaintiffs have alleged, in effect, that the F.D.A. has systematically attempted to discredit Krebiozen and to prevent its introduction into commerce."

The same would be true with respect to the Department of Biologic Standards if application for interstate distribution of Krebiozen under the Public Health Service Act is made for purposes of sale, barter and exchange.

However, even if approval is granted for interstate commercial distribution of Krebiozen, so long as the conspiracy remains unenjoined the respondents will effectively prevent its general availability to the suffering public through the continuing reference to the medical profession of the past and of the future fraudulent and misleading publications denying its efficacy, and through continuing professional and economic disciplining of all physicians, hospitals and clinics daring to use it.

6, 7, 8. The sole defense of the Respondents that the statutory procedure under the Federal Food, Drug and Cosmetic Act must be first exhausted is invalid since Krebiozen comes instead under the Public Health Service Act and since it is immaterial whether or not Krebiozen comes under either Act so long as the alleged conspiracy prevents their proper legal implementation.

As correctly stated in the opinion of the District Court on July 18, 1966 (Vol. II, p. 532, R.):

> "The prayer for relief seeks an order enjoining the defendants 'from impeding, hindering, or impairing the free *uncommercial* flow of Krebiozen interstate * * * to the physicians of the plaintiffs * * * for the purpose of continuing experimentation on the plaintiffs by their doctors.'"

The District Court then went on to write (Vol. II, pp. 532-534, R.):

> "Krebiozen is a 'new drug'; introduction of new drugs into interstate commerce is governed by 21, U.S.C. section 355, subsection (a) of which provides as follows:
>
> > "'No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.'
>
> "Subsection (b) provides for a detailed application, including reports of tests made of the drug, a statement of the composition of the drug, a description of the methods and conditions of manufacture, and samples of the drug if requested. The application by a person who wishes to 'introduce or deliver for introduction into interstate commerce' the drug in question."

The District Court was correct in the first instance that what was sought was relief from restraining "uncommercial" flow of Krebiozen interstate for use in scientific and experimental research. Then it strayed far afield from the subject, and in grevious error because Krebiozen is *not* a "new drug", and is *"not"* governed by 21 U.S.C. or any other provision of the Federal Food, Drug, and

Cosmetic Act. This has been determined on three different occasions by the Department of Health, Education, and Welfare, and any application "filed pursuant to subsection (b) of this section" would be futile and has been futile.

What is classified as a "new drug" under the Federal Food, Drug, and Cosmetic Act, is not within the jurisdiction of the courts or the Attorney General to decide. This comes within the jurisdiction of the scientific expertise of the Department of Health, Education, and Welfare to determine. In mid-March 1954, the sponsors of Krebiozen did file an application with the Department of Health, Education, and Welfare under subsection (b), section 355, Title 21 U.S.C. On May 25, 1954 the application was rejected and refused, not on the merits, but because the Department of Health, Education, and Welfare ruled as follows:

> "* * * it is the considered view of the Department of Health, Education, and Welfare that Krebiozen is subject to the Virus, Serum, Toxin provisions of the Public Health Service Act of July 1944, and that the article may not be legally marketed in interstate commerce until licensed under the provisions of that Act.
>
> "* * * *When a license is issued by that unit of the Department, an effective new drug application under the Federal Food, Drug, and Cosmetic Act is not required.*
>
> *"Even if a new drug application became effective for the article, it would still be necessary that it be licensed under the provisions of the Public Health Service Act in order that it be distributed in interstate commerce.*
>
> *"Nothing is to be gained by considering the product as a new drug under the Food, Drug, and Cosmetic Act. It is therefore our suggestion that you take ap-*

propriate steps looking toward the issuance of a license for the article by the Laboratory of Biologics Control.''

Immediately after the determination of the Department of Health, Education, and Welfare of May 25, 1954, the sponsors of Krebiozen submitted additional data to the Department of Health, Education, and Welfare in an effort to show that Krebiozen did come within the provisions of the Federal Food, Drug, and Cosmetic Act. This, again, was rejected on August 12, 1954 as follows:

"Our scientists, on the information submitted, classify this drug as an 'analogous product' within the meaning of the Public Health Service Act.

"Since the drug, in the Department's view, may not be distributed for *barter or sale* unless produced in a licensed establishment, we recommended to you in our letter of May 25, that you take the problem up with the Laboratory of Biologics Control *rather than pressing for an effective new drug application.* The Department can hardly construe the two laws [illegible] that one stituent would apparently approve interstate distribution of a drug by permitting a new drug application to become effective while the more directly concerned constituent regarded the distribution as a contravention of the law enforced by it.

"We do not insist on the needless duplication of satisfying the requirement of both laws. We do insist, however, that products subject to license control meet the requirements of the Public Health Service Act. When they do, safety is assured and *a new drug application is not necessary.*

"We renew our recommendation that you take steps to obtain a license rather than making further efforts to complete the new drug application.''

The efforts of the sponsors of Krebiozen to have the article classified as a product coming within the provisions of the Federal Food, Drug, and Cosmetic Act were practical because in 1954 up to 1963 all that was required to put a drug into interstate commerce was that the drug was safe. On the other hand, to put drugs into interstate commerce which came within the provisions of the Public Health Service Act, both safety and effectiveness were required. At this time, under neither law was there any restriction as to interstate distribution of drugs for use in scientific and experimental research and which were not for sale, barter, or exchange. There is still no restriction for such distribution under the provisions of the Public Health Service Act under which Krebiozen comes. Again, in 1961, the sponsors of Krebiozen made another effort to have Krebiozen classified as a "new drug" under the provisions of the Federal Food, Drug, and Cosmetic Act by submitting additional data as to its components, and again the application was rejected on the same grounds as follows:

> "Until data are submitted convincingly demonstrating that Krebiozen is a hormone within the meaning of the Public Health Service Regulations the article will be regarded as subject to the licensing provisions of the Public Health Service Act. *When it is licensed an effective new drug application is not required.* The article cannot be legally marketed in interstate commerce until it is licensed under the Public Health Service Act.
>
> *"We recommend that you abandon the idea of pursuing an effective new drug application and submit an appropriate application for licensing of Krebiozen by the Division of Biological Standards, National Institutes of Health, U.S. Public Health Service."* (all underscoring supplied)

The latter determination by the Department of Health, Education, and Welfare was rendered on June 9, 1961. (For rejections in 1954, see pp. 151-154, Vol. III, Record).

What has happened in this case is simple. The respondents know the allegations in the Complaint are true, and they know that the facts alleged and provable constitute serious violations of the Sherman Act and the Civil Rights statutes. They also know that cancer is widespread among the under-privileged, the class that can least afford the luxury of present expensive surgery, hospitalization, narcotics, radiation therapy and similar orthodox, and admittedly largely ineffective, treatment—the class that will be most benefitted by an inexpensive non-toxic treatment such as Krebiozen. The Court of Appeals clearly recognized this when it characterized this suit as follows:

> " * * * the complaint is an outcry of hopeless, suffering cancer victims who lack the funds required by the recognized cancer therapies, and who believe in the ameliorative and curative properties of the now well publicized drug, Krebiozen."

In an attempt to avoid answering these allegations, they admit them, but seek immunization from the violations by relying on a defense based on the proposition that the determinations of the Department of Health, Education, and Welfare in 1954 and 1961 were erroneous, and for this reason they claim the right to conduct such a conspiracy in order to enforce what they claim is the law. For the first time in the judicial history the courts below have sustained such a claim, and even went further that this defense operates retroactively for over 13 years prior to the enactment of the law relied on. Such a defense, of course, is not available. *American Medical Association*

v. *United States,* 130 F. 2d 233, 246, affirmed, 317 U.S. 519. Moreover, if it be held by this Court that the determinations of the scientific expertise of the Department of Health, Education, and Welfare in 1954 and 1961 were in error—and such a possibility is impossible to imagine—and that Krebiozen does come within the provisions of the Federal Food, Drug, and Cosmetic Act, then the respondents and the Courts are caught with no choice but between the rock and the whirlpool, because if it be held that this article does come within the provisions of the Federal Food, Drug, and Cosmetic Act, then the applications made under subsection (b), 355, Title 21, U.S.C. in 1954 and in 1961 became effective under section 355 (c) because they were not denied on the merits within the time made mandatory by that subsection which, under the law as it stood at the time, the article was already in interstate commerce by default. Subsection 355 (c) in 1954 and 1961, provided as follows:

> *"Effective date of application*
>
> *"(c) An application provided for in subsection (b) of this section shall become effective on the sixtieth day after the filing thereof, unless prior to that day the Secretary by notice to the applicant in writing postpones the effective date of the application* (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application."

It is all around conceded that the application was not denied on the merits within the 60-day limitation provided by section 355(c), nor was there any extension of time beyond this limit taken by the Secretary, nor was such mandatory notice given to the applicant prior to the sixtieth day of its filing, nor was there any "notice to the applicant in writing" that further time was required by the Secretary to "investigate the application." Instead

of holding that Krebiozen is subject to that Act and accordingly complying with the statutory permissible action within the now passed statutory time limit, the Secretary in each instance, as set forth above, ruled that the Act itself does not apply to Krebiozen.

9. Krebiozen being subject only to the Public Health Service Act can be freely distributed interstate so long as not for sale, barter, or exchange, without Federal approval.

All articles which are governed by the Public Health Service Act may be legally distributed interstate for "use in scientific and experimental research" so long as they are not for "sale, barter, or exchange." Section 262, Title 42, U.S.C. prescribes the requirements for putting these articles into interstate commerce. The statute is penal, and is directed against persons who send, carry, or bring into the United States, or from one state to another, articles which come under the provisions of the statute, for "sale, barter, or exchange" and against such persons only. Being a penal statute, the natural meaning of the words "sale, barter, or exchange", defining the offense and the class of offenders cannot be enlarged by construction because of any underlying intent. These words contain no ambiguity whatever. This has always been rigidly adhered to by this Court. *United States* v. *Wiltberger,* 5 Wheat. 76, 95; *Sturges* v. *Crowinshield,* 4 Wheat. 122, 202; *Lake County* v. *Rollins,* 130 U.S. 662, 670; *United States* v. *Baltimore and Ohio Southwestern Railroad Company,* 222 U.S. 8. That has been the construction given to this particular penal statute by the Attorney General for over 50 years. 29 Opinion of Attorney General 340. Krebiozen as it does, coming within the provisions of the Public Health Service Act is not prohibited from interstate distribution for "use in scientific and experimental research."

10. The regulations authorized under the Federal Food, Drug and Cosmetic Act cannot be engrafted on the Public Health Service Act so as to govern Krebiozen as an "analogous" product, not subject to the former Act, but instead to the latter Act.

Congress in granting the secretary of Health, Education, and Welfare the authority to promulgate regulations by the amendment of section 355(i), Title 21, U.S.C. neither explicitly or by implication authorized that such regulations should be extended to articles governed by the Public Health Service Act. On the contrary, the grant is expressly limited to drugs solely for investigational use which come within the provisions of the subsections (a) to (h) foregoing subsection (i), and this is further made clear that the regulations are for the explicit purpose which "will enable him (the Secretary) to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section." Krebiozen does not come within the subsections of section 355, Title 21, U.S.C. foregoing subsection (i), and as pointed out in the previous paragraphs there can be no "event of the filing of an application pursuant to subsection (b) of this section." To add regulations to a statue under the Public Health Service Act which Congress did not think necessary to prescribe would not be regulation, but legislation. The object sought by the respondents or even by the Secretary of Health, Education, and Welfare can only be accomplished by an amendment to the statutes of the Public Health Service Act. This is not the office of the respondents, or the Secretary of Health, Education, and Welfare. *Morrell* v. *Jones,* 106 U.S. 466; *United States* v. *United Verde Copper Company,* 196 U.S. 207; *United States* v. *Standard Brewery,* 251 U.S. 210.

11, 12. Insofar as the Federal Food, Drug and Cosmetic or any other Federal Act can be applied to inhibit the practice of medicine, the control of which is exclusively in the States, such an Act is unconstitutional.

No intelligent student of law, or any Justice of this Court, will deny that the practice of medicine comes exclusively within the powers reserved by the States, and is guaranteed against infringement by any agency of the Federal Government through the Tenth Amendment, and to the same extent, that the Fourteenth Amendment guarantees all of the rights and privileges secured by all of the Constitution and all of laws of the United States against State infringement. *United States* v. *Price*, 383 U.S. 787. That the practice of medicine is exclusively a State right, does not lessen its importance. Few will deny that it is the inherent and pre-constitutional right of the people to have the benefits of the services of the medical doctor. If the laws of the States are in violation of the rights guaranteed by the Fourteenth Amendment, they are void. To the same extent, if a federal law infringes on the rights reserved by the States they are also void under the Tenth Amendment. And if either a State or Federal law violates the inherent rights reserved by the people by the Ninth Amendment it is void. Section 355(i), Title 21, U.S.C., under the construction given it by the respondents would be such an invalid law because it infringes on the rights of doctors to practice their calling, and the inherent rights of the people to have the benefits of this medical science. If the construction of the respondents is sustained, then Congress has, under the pretext of the Commerce Clause, passed a law for the accomplishment of an object not intrusted to the Federal Government, as the practice of medicine is not naturally and reasonably

adapted to the effective use of that power, because this is a power exclusively within the power reserved for the States. This has long ago been settled by this Court. *Linder* v. *United States*, 268 U.S. 5.

Under the Constitution, doctors of medicine, must by the very nature of their profession in the preservation of life, have free and immediate access to medical remedies, orthodox or unorthodox, where in their opinion such remedies might save or prolong the lives of their patients. To ascertain the limited or the unlimited function of the doctor in the area of doctor-patient relationship, we must search in the laws of the State, because the Federal law can have no application or any impact on this profession. To the extent that it would have, the law would be unconstitutional.

Undoubtedly, the Federal Government can enact laws or authorize the promulgation of regulations, and prescribe certain conditions when it is sought to introduce into interstate commerce and drug, and its effect on such commerce, or even to its safety. Through its health agencies it could make suggestions as to the efficacy of such drug in treating a particular disease. But in the final analysis this efficacy is exclusively within the judgment of the doctor administering the proposed remedy. This is so because the efficacy of the remedy is not a matter of fact, but merely an opinion, and not the opinion of any particular school of medicine, but of the doctor administering it. The different schools of medicine have their followers, and many who believe in one will pronounce the other wholly devoid of merit. However, "there is no precise standard by which to measure the claims of either, for people do recover who are treated according to the one or the other school. * * * It is a question of opinion in

all of the cases, * * * yet after all it is in each case opinion only, and not existing facts with which these cases deal." *School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94, 103-104. Probably the best example of this can be found in *Stammer* v. *Board of Regents*, 262 A.D. 372, affirmed 287 N.Y. 359. There a doctor effected a cure for cancer when the approved and so-called orthodox methods of treatment had proved futile, and he was punished for it. What the State law is on the practice of medicine was clearly outlined in that case, and the ruling on that case and similar State cases is binding on the Federal Government. It was held that any restrictions which stifle initiative and originality on a doctor in the practice of medicine already skilled in the medical art, in attempting new methods of saving a life, especially when undertaken with the patient's full knowledge and consent, and on a strictly patient-doctor relationship, and not for experiment for the sake of experiment, but an attempt to prevent death, or prolong a life, when all known and so-called orthodox methods of treatment have failed, and when the patient's very life had been despaired of, such restrictions are unlawful. It is equally unlawful against the Federal Government where it imposes the restrictions.

The wrong is all the more aggravated when this stifling of initiative and originality in the "Progress of Science and the useful arts" is the result of a criminal conspiracy conducted by two corporations, a State University, and a series of individuals, in violation of the Sherman Act as the facts in the instant case reveal, and violates Article 1, section 8, of the Constitution concerning the "Progress of Science and the useful arts", and the Fifth, Ninth, Tenth, and Fourteenth Amendments of the Constitution. This question of such immense social significance, standing alone, warrants review on certiorari by this Court because

this is a class action in behalf of over 300,000 Americans, who, according to statistics, will die within the next year, not only with cancer but from cancer.

13. The District Court was in error when it ruled that Krebiozen came within the provisions of the Federal Food, Drug, and Cosmetic Act. In its opinion on July 18, 1966 (Vol. II, p. 534, R.) it wrote:

> "Plaintiffs claim that Krebiozen's sponsors need not invoke the remedy provided by Congress. However, it is too well settled to require extended discussion that where Congress creates an expert administrative agency to perform a specific regulatory task which requires expertise, the agency cannot be bypassed. All matters properly within the agency's scope of authority must be referred to this agency for action in the first instance."

We have no quarrel with the determinations of the Department of Health, Education, and Welfare. On the contrary we have prayed that they be enforced and obeyed, and have asked the courts to sustain them, and make its judgment in accordance with them: that Krebiozen comes within the provisions of the Public Health Service Act, because as determined by the Department of Health, Education, and Welfare nothing is to be gained by an application under the Federal Food, Drug, and Cosmetic Act, and coming as it does, under the Public Health Service Act, it may be distributed interstate for "use in scientific and experimental research" when not for "sale, barter, or exchange." Section 262, Title 42, U.S.C.; 29 Opinion of Attorney General 340. It is the respondents that challenge the determination of the Department of Health, Education, and Welfare, not the petitioners. They use this as a flimsy defense to justify a conspiracy in violation of the antitrust laws. Then the District Court went on to write in the next paragraph:

"This rule applies to Krebiozen, even though the complaint in this case is framed in terms of the civil rights and the anti-trust statutes. Clearly, until an invocation of the provisions of section 355 has proved fruitless, there is no possible equitable relief that can be granted that does not directly interfere with the FDA's jurisdiction. Whatever injury plaintiffs presently suffer as a result of restrictions on interstate distribution of Krebiozen is the result of the operation of the Food, Drug and Cosmetic Act, *and not of illegal activity by the defendants.*" (emphasis supplied)

Both the District Court and the Court of Appeals rely on *Turkel* v. *Food and Drug Administration*, 334 F. 2d 844. To one versed only in the English language this is very difficult to comprehend as under the determinations of the scientific expertise of the Department of Health, Education, and Welfare concerning both Krebiozen and Dr. Turkel's "U" Series drug, there can no more be a valid license issued for "U" Series under the provisions of section 262, Title 42, U.S.C., than there can be an effective application for Krebiozen under section 355 (b), Title 21, U.S.C., the Federal Food, Drug, and Cosmetic Act. It is as simple as that. Nor can there be a valid indictment or injunction sanction for a violation of section 262, Title 42, U.S.C. where the "U" Series drug is concerned, any more than there can be a valid indictment or injunction sanction for a violation of section 355 (b), Title 21, U.S.C. of the Federal Food, Drug, and Cosmetic Act, where Krebiozen is concerned. The indictment found against the sponsors of Krebiozen under the Federal Food, Drug, and Cosmetic Act in 1964, which culminated in a verdict of "not guilty" was not worth the paper it was written on. If there was a violation at all, it was under section 262, Title 42, U.S.C. It was held in Turkel, that a direct appeal

to the United States Court of Appeal could have been perfected had Dr. Turkel been denied an effective application under section 355 (b), Title 21, U.S.C. As to Krebiozen, the Department of Health, Education, and Welfare has held on three occasions that there can be no valid "event of the filing of an application pursuant to subsection (b) of this section." This should completely rule out the *Turkel* Case as authority for use in the present litigation.

14, 15. That the questions of irreparable damage and loss to the liberty and lives of the petitioners were raised at all on February 4, 1967, and May 13, 1967 was sufficient on which to grant a hearing and make findings of fact and conclusions of law under Rule 52, of the Federal Rules of Civil Procedure. It is elementary in law that premature expressions by the District Court predicting the ultimate and, in fact, the inevitable disposition of the case rendered as to the issue before it, or any issue on the merits useless. The District Court determined right there and then such disposition, and all the Court's subsequent actions were made with the already predetermined disposition as the goal. These premature expressions are that "Cancer sufferers should have no illusory hope that any legal action involving Krebiozen can provide them with the relief they seek, for those hopes are almost certain to be destroyed in frustration.

The only credible hope, course of hope, is through the FDA, and, if necessary, the system of careful review of FDA action. That is the only route by which Krebiozen has a chance at all of being freed from the present bans imposed upon it.

This lawsuit, and all lawsuits like it, are doomed to failure." (Vol. II, p. 365, R.) In the first instance, as pointed out before, there can be no FDA action, and no "system

of careful review of FDA action." That has been determined by the Department of Health, Education, and Welfare. It is elementary in law that the opinion delivered from the bench cannot substitute for the special, formal, and mandatory findings by which it is the duty of the Court appropriately and specifically to determine the issues before it, and such issues to be determined on these particular applications concerned the confiscation of life. In such a case the plaintiffs had a plenary right to have a factual showing on the probable confiscatory effect of the alleged criminal conspiracy of that life, and be allowed to demonstrate by competent legal evidence the propriety in the interest of justice, and in order to prevent continued irreparable injury to life until a final hearing on the merits could be had. This is in conformity with the long standing and salutary principle that essential facts should be determined before passing on the grave constitutional, Civil Rights, and other rights in this case and the alleged violation thereof. *Polk Company* v. *Glover,* 305 U.S. 5; *Borden's Farm Products* v. *Baldwin,* 293 U.S. 194; *Mayo* v. *Lakeland Highlands Canning Company,* 309 U.S. 310; *Railroad Commission* v. *Maxcy,* 281 U.S. 82. Observations expressed in an opinion not based on facts are not such findings.

16. The inherent right to survival guaranteed by the Fifth, Ninth and Fourteenth Amendments includes the right of an individual to access to a non-toxic remedy of his own free choice which he himself judges to be indispensible for his life.

The right to freedom of survival is the primary right upon which all other rights depend: unless one survives all other rights are of no value and without use.

The American Medical Association in concert with the other respondents have now conducted for over fifteen years a studied course of action and effective propaganda to destroy a medical remedy for cancer, which is non-toxic, effective and would be inexpensive—a remedy that obviates surgery, extensive hospitalization, narcotics, and radiotherapy. But, therefore, it will eliminate the vast income presently received by the medical establishment derived from such orthodox treatment. Krebiozen inevitably confronts the medical establishment with the choice of promoting and definitely testing this independently discovered non-toxic remedy to the detriment of its economic interests and prestige of discovery, or to hinder its development and to destroy it in order to protect such interests. As in similar instances of independent discovery in the past, it has chosen the latter course. As a direct result of this conspiracy the major portion of some 300,000 victims of cancer have now needlessly died each year during this conspiracy, an unnecessary sacrifice in human life in the aggregate so great as to be difficult to comprehend or entertain.

If the decisions of the District Court and the Appellate Court are not reversed by this Court it will now be established in this country that in medical matters the American Medical Association is in fact and practice immune to suit of private individuals and, as to them, supreme and even superior to the Government, the Courts, and the Constitution.

17. The Federal Food, Drug and Cosmetic Act by reason of its statutory permissible delay of approval thereunder and of further extended delay in administrative and thereafter judicial appeals violates the rights

of the petitioners and others, to whom such delays are fatal, under the Fifth, Ninth and Fourteenth Amendments.

The Amendment of 1961 to the Federal Food, Drug and Cosmetic Act known as the "Kefauver Amendment" added the requirement of proof of effectiveness of a new drug to the satisfaction of the personnel staffing the Food and Drug Administration before access to such a medical remedy could be available to patients, otherwise declared hopeless, whose survival depends upon such a remedy. Prior to an application for an approval it is necessary to obtain and assemble, at an expense usually beyond reach, of private individuals and independent researchers, such voluminous and technical scientific production and clinical data as these employees may insist upon, as a precondition for their consideration of the effectiveness of a new drug. If such personnel choose capriciously or arbitrarily to deny such investigational exemption there is no right of judicial appeal: *Turkel* v. *F. D. A.*, 6 Cir. 334 F. 2d 844 (1964). Furthermore, if and when an application is made directly for approval of interstate commerce distribution the Secretary of Health, Education and Welfare can, under that Amendment, delay for more than half a year, after the application is made before approving it: 21 U.S.C.A. 355(c).

If he capriciously or arbitrarily refuses approval, resort must first be had by the applicant to administrative appeals and only thereafter to the Courts for judicial appeal: 21 U.S.C.A., section 355(h).

In the meantime, as would happen in the case of Krebiozen, were it a new drug and therefore subject to that Act, those whose lives exclusively depend upon access to such new drug have long since, painfully expired. Any eventual success on appeal is for them but a pyrrhic victory.

The Act as thus amended therefore clearly violates the right to survival of such unfortunate and forgotten victims. As to them this Act is clearly, unconstitutional and fatally defective because not providing for temporary exception and relief prior to approval to all whose survival uniquely depends upon a new drug.

The District Court and the Court of Appeals in this case have now established, if their decisions are not reversed by this Court, that this fatal gap will not even be cured by judicial relief in the form of a temporary injunction.

Had the Kefauver Amendment provided instead that a sponsor of a new drug could not represent to the public that it is effective, until such effectiveness was approved by the Food and Drug Administration, and prior to that time must represent that such recognition of effectiveness had not been yet obtained, then it would have accomplished the salutary objective of preventing the foisting on the public of new drugs represented to be effective when in fact not proved effective—without, however, having subjected the basic right of free choice of a physician or a patient of an indispensable medical remedy to possible fatal restriction and delay.

Krebiozen is a glaring illustration as to how the power of Governmental control under such a statute can be exercised, not for the good of the public, primarily, but instead for the benefit of the economic and prestige interests of the American Medical Association, in the case of any new fundamental, independently developed medical remedy that may conflict with its interests.

SUMMARY

To fully understand this case the position of the American Medical Association as *respondeat superior* must be observed as a stark realism. This Association conjointly with and through the other respondents, have endeavored for seventeen years to destroy the independently developed non-toxic, anti-cancer therapy, Krebiozen. This they admit. The purpose is to preserve the monopoly alleged because if this therapy was introduced into medicine, and it proved effective in the treatment of cancer, it would render obsolete the major portion of current surgery, radiation, chemotherapy, narcotics, long and expensive hospital and nursing care. It has successfully prevented its adoption through fraudulent publications in authoritive medical journals under its control, through suppression of voluminous scientific reports evidencing its effectiveness in the control of cancer, through thwarting any definitive scientific clinical tests, and through economically and professionally disciplining all physicians, clinics and hospitals daring to investigate it.

Both the courts below have now, in the instant case, denied the present application. They have effectively prevented the exposure and proof of this illegal course of conduct by the American Medical Association which, if sustained by this Court will destroy all independent research on cancer. If the petitioners are heard, this would establish the validity and availability of this therapy which could save the lives of 300,000 Americans destined to die from cancer within the next year because the American Medical Association must preserve the monopoly on therapies which are profitable and at the same time ineffective in the treatment of the disease.

In so doing the courts below have failed or refused to recognize, or where so recognizing them, have refuted, without a hearing of the facts, the allegations of these unfortunate citizens. They have dismissed their application made under the law where "Any person, * * * may sue for and have injunctive relief from threatened loss or damage by violation of the antitrust laws." (Section 26, Title 15, U.S.C.). These courts have instead, dismissed the application of these petitioners and in complete disregard of their constitutional rights. In so doing they have furthered the extension of control of the American Medical Association and authorized that criminal conspiracy is a valid weapon to enforce law. Under such ruling the monopolistic control held by the American Medical Association has not only become more effective, but validated.

If the decision of the courts below is not reversed the abolition of civil rights will be an established fact sanctioned by the judiciary in so far as medical remedies are concerned. It will have established that we are now all the virtual slaves of this Combination in so far as our health is concerned.

It is now common knowledge that independently discovered and developed market advances in medical science have been deliberately delayed by this Association for years. It had attempted to destroy Group Health Plans by the same tactics as used in this case. *American Medical Association* v. *United States,* 130 F. 2d 233, affirmed 317 U.S. 519. Numerous other advances in medicine have been falsely labelled as "Quack Remedies" and destroyed. Those which have broken through are merely the top of the iceberg and have little relation to those still under the surface. The Salk vaccine was so branded and delayed for six years and its acceptance finally forced by a group of the laity in the "March of Dimes" under the impetus

of the then President of this Republic. Sabin had to obtain such a body of clinical proof that it could not be gainsaid, by going to another (and, in this respect, scientifically freer) country, the Soviet Union. Penicillin, progenitor of present anti-biotics, discovered by Fleming, a chemist, was derided for more than ten years, and its recognition only finally forced by the Army in the Second World War. The same resistance attended the discoveries, such as "606" by Ehrlich, smallpox vaccination by Jenner, antisepsis in surgery by Holmes, Lister, and Keen, microbes by Pasteur, aberrations by Freud, sanitation in children by Semmelweis, and even circulation of blood by Harvey.

In each and every instance this Association, and before it orthodox medicine as then constituted, resisted such independently developed profound medical advances either because detracting from its prestige, and today thereby jeopardizing justification for continuation of vast research grants, or because threatening obsolescence of current medical practices with attendant temporary economic hardship and readjustment to its members. In all instances the incidental continuation of loss of life or of pain to thousands of sufferers has been given only subordinate consideration.

This present suit represents the first instance where such sufferers as the Petitioners, have themselves raised their voices and applied to the Courts of the land for the elemental right of a judicial hearing in which to substantiate any controverted allegations as to a repetition of this course of conduct by the respondents, in this instance with respect to the independently discovered medical remedy for cancer, Krebiozen. Five of them have died during the attempt. If denial of judicial review of this alleged conspiracy is delayed sufficiently longer the respondents will prevail as the suit will become moot.

The Courts below, however, stand aghast at the thought of such a "frontal attack" against so powerful and "sacred" a combination of these Respondents—and at every step have thwarted any opportunity for a hearing on the facts—even though these petitioners, anticipating such a mistaken reaction, have thoroughly documented their pleadings with verified evidentiary exhibits as prima facie justification of the substantiality of their application.

On the record of this case these petitioners, already given up as "hopeless" by these respondents, now petition this Court to reverse the refusal of the courts below to afford them a hearing, and aver that if such is not granted a denial by this Court will not only be at the expense of their survival and freedom of pain, but at such expense to thousands of other Americans presently suffering from pronounced "incurable" cancer.

CONCLUSION

For the foregoing reason, on this application, the judgment of the Court of Appeals should be vacated, and the case remanded to the District Court for a hearing on the facts, or in the alternative, the writ of certiorari should be granted and the case put on the docket for primary consideration.

Respectfully submitted,

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